What is claimed is:

1. A controlled release dosage form comprising azithromycin and a pharmaceutically acceptable carrier which, following ingestion by a mammal in need thereof, releases azithromycin to said mammal's gastrointestinal tract at a rate such that the total amount of azithromycin released therein is:

not more than about 4 mg of azithromycin per kg of mammal weight in the first 15 minutes after ingestion,

not more than about 10 mg of azithromycin per kg of mammal weight in the first hour after ingestion,

not more than about 20 mg of azithromycin per kg of mammal weight in the first 2 hours after ingestion,

not more than about 30 mg of azithromycin per kg of mammal weight in the first 4 hours after ingestion, and

not more than about 40 mg of azithromycin per kg of mammal weight in the first 6 hours after ingestion

2. A controlled release dosage form comprising azithromycin and a pharmaceutically acceptable carrier which, following ingestion by a mammal in need thereof, releases azithromycin to said mammal's gastrointestinal tract at a rate such that the total amount of azithromycin released therein is:

not more than about 200 mg of azithromycin in the first 15 minutes after ingestion,

not more than about 500 mg of azithromycin in the first hour after ingestion,

not more than about 1000 mg in the first 2 hours after ingestion,

not more than about 1500 mg in the first 4 hours after ingestion, and

not more than about 2000 mg in the first 6 hours after ingestion.

3. A dosage form as defined in claim 2, wherein said azithromycin is embedded in a matrix, which releases said azithromycin by diffusion.

4. A dosage form as defined in claim 3, wherein said matrix remains substantially intact during the period of drug release.

5. A dosage form as defined in claim 3, wherein said azithromycin is embedded in a matrix which releases said azithromycin by eroding.

6. A dosage form as defined in claim 5, wherein said matrix comprises hydroxypropyl methylcellulose.

7. A dosage form as defined in claim 5, wherein said matrix comprises hydroxypropyl cellulose.

8. A dosage form as defined in claim 5, wherein said matrix comprises poly(ethylene oxide).

9. A dosage form as defined in claim 5, wherein said matrix comprises polyacrylic acid.

10. A dosage form as defined in claim 2, comprising a reservoir of azithromycin encased in a membrane which limits the release rate of azithromycin to said GI tract by diffusion.

11. A dosage form as defined in claim 10, in the form of a tablet coated with a membrane.

12. A dosage form as defined in claim 2, in the form of a multiparticulate comprising particles each of which is coated with a membrane which limits the release rate of said azithromycin by diffusion.

13. A dosage form as defined in claim 3, wherein a portion of the outside surface of said matrix is covered with an impermeable coating and the remainder of said outside surface is uncovered.

14. A dosage form as defined in claim 13, substantially in the shape of a cylinder wherein said impermeable coating covers one or both of the opposing flat surfaces thereof.

15. A dosage form as defined in claim 13, substantially in the shape of a cylinder wherein said impermeable coating covers only the radial surface thereof.

16. A dosage form as defined in claim 13, in the form of a tablet, wherein said uncovered area is in the form of an opening through said impermeable coating.

17. A dosage form as defined in claim 13, in the form of a tablet, wherein said uncovered area is in the form of a passageway which penetrates through the entire device.

18. A dosage form as defined in claim 13, in the form of a tablet, wherein said uncovered area is in the form of one or more slits through said impermeable coating or in the form of one or more strips removed therefrom.

19. A dosage form as defined in claim 13, substantially in the form of a cone, wherein the uncovered area an opening for drug transport at or near the apex of the cone.

20. A dosage form as defined in claim 13, substantially in the shape of a hemisphere, wherein the uncovered area is in the form of an opening for drug transport at or near the center of the flat face of the hemisphere.

21. A dosage form as defined in claim 13, substantially in the shape of a half-cylinder, wherein the uncovered area is in the form of one or more slits at or near the centerline of the flat face of said half-cylinder.

22. A method for administering azithromycin to a human in need of such treatment, comprising orally administering said azithromycin to said human in a dosage form which effects release of said azithromycin into the GI tract at a rate such that the total amount of azithromycin released therein is;

less than about 200mg in the first 15 minutes following ingestion,
less than about 500 mg in the first hour following ingestion,
less than about 1000 mg in the first 2 hours following ingestion,
less than about 1500 mg in the first 4 hours following ingestion, and
less than about 2000 mg in the first 6 hours after ingestion.

23. A process for preparing a multiparticulate dosage form of azithromycin according to claim 1 or claim 2 comprising the steps of:

(a) granulating azithromycin bulk drug substance with a binder to obtain a granulation having an average particle size from about 50 to about 300 μM;

(b) substantially immediately thereafter coating the granulated azithromycin with a sustained release membrane-forming material in an amount of about 5 to 30% of the total weight of the coated product; and

(c) thereafter further coating the product of said step (b) with additional polymer until the total amount of polymer coating is from about 25% to about 70% of the total weight of the coated product.

24. A process as defined in claim 23, comprising the additional step of coating the product of step (c) with a pH-sensitive polymer which is soluble at a pH > 6, but insoluble at a pH < 4.

25. A process as defined in claim 24, wherein the sustained-release polymer is ethylcellulose and the pH-sensitive polymer is a copolymer of methacrylic acid and methylmethacrylate or cellulose acetate phthalate.

26. A dosage form for oral administration comprising azithromycin and a pharmaceutically acceptable carrier, which releases not more than 10% of its incorporated azithromycin into a mammal's stomach, and which releases not more than an additional 10% during the first 15 minutes after entering said mammal's duodenum.

27. A dosage form as defined in claim 26, wherein said mammal is a human.

28. A dosage form as defined in claim 26, in the form of a tablet.

29. A dosage form as defined in claim 26, comprising a multiparticulate having a diameter between about 0.5 mm and about 3 mm.

30. A dosage form as defined in claim 26, comprising a multiparticulate having a diameter between about 0.1 and about 0.5 mm.

31. A dosage form as defined in claim 28, coated with a membrane comprising a polymer which is substantially insoluble and/or impermeable to azithromycin at the pH of the stomach, and is soluble and/or permeable to azithromycin at the pH of the small intestine and colon.

32. A dosage form as defined in claim 31, wherein said polymer is selected from cellulose acetate phthalate, polyvinylacetate phthalate, hydroxypropyl methylcellulose phthalate, and copolymers comprising acrylic acid and at least one acrylic acid ester.

33. A dosage form as defined in claim 29, wherein said multiparticulate are coated with a membrane comprising a polymer that is substantially insoluble and/or impermeable to azithromycin at the pH of the stomach, and is soluble and/or permeable to azithromycin at the pH of the small intestine and colon.

34. A dosage form as defined in claim 33, wherein said polymer is selected from cellulose acetate phthalate, polyvinylacetate phthalate, hydroxypropyl methylcellulose phthalate, and copolymers comprising acrylic acid and at least one acrylic acid ester.

35. A dosage form as defined in claim 30, wherein said particles are coated with a membrane comprising a polymer that is substantially insoluble and/or impermeable to azithromycin at the pH of the stomach, and is soluble and/or permeable to azithromycin at the pH of the small intestine and colon.

36. A dosage form as defined in claim 35, wherein said polymer is selected from cellulose acetate phthalate, polyvinylacetate phthalate, hydroxypropyl methylcellulose phthalate, and copolymers comprising acrylic acid and at least one acrylic acid ester.

37. A dosage form as defined in claim 28, wherein said tablet optionally further comprises one or more osmagents, said tablet being surrounded by a semipermeable membrane that is permeable to water and substantially impermeable to said azithromycin and said osmagents.

38. A dosage form as defined in claim 29, said multiparticulate furth r comprising one or more osmagents, said multiparticulate being surrounded by a semipermeable membrane that is permeable to water and substantially impermeable to azithromycin and osmagents.

39. A dosage form as defined in claim 28, further comprising at least one swellable material, said tablet being surrounded by a semipermeable membrane that is permeable to water and substantially impermeable to azithromycin and said swellable material.

40. A dosage form as defined in claim 29, further comprising at least one swellable material, each of said multiparticulate being surrounded by a semipermeable membrane that is permeable to water and substantially impermeable to azithromycin and said swellable materials.

41. A dosage form as defined in claim 28, comprising:

a core comprising azithromycin and at least one osmagent;

a wall surrounding said tablet comprising a semipermeable membrane which is permeable to water and substantially impermeable to azithromycin and osmagent; and

a pH-sensitive trigger means attached to said semipermeable membrane for triggering the bursting of the tablet, said trigger means triggering at a pH between 3 and 9.

42. A dosage form as defined in claim 29, said multiparticulate each further comprising

one or more osmagents, each multiparticulate being surrounded by a wall comprising a semipermeable membrane which is permeable to water and substantially impermeable to azithromycin and osmagent; and

a pH-sensitive trigger means attached to said semipermeable membrane for triggering the bursting of the multiparticulate said trigger means triggering at a pH between 3 and 9.

43. An azithromycin dosage form as defined in claim 41, wherein said core further comprises at least one swelling material.

44. An azithromycin dosage form as defined in claim 42, wherein said multiparticulate further each comprise at least one swelling material.

45. A dosage form as defined in claim 28, comprising:
a core comprising azithromycin and at least one osmagent;
a membrane surrounding said tablet core wherein said membrane is fabricated from a microporous hydrophobic support material;
a hydrophobic liquid entrained within said membrane, said hydrophobic liquid being substantially impermeable to water and azithromycin, but being capable of changing to become substantially permeable to water and azithromycin.

46. A dosage form as defined in claim 29, comprising:
a core comprising azithromycin and at least one osmagent;
a membrane surrounding said multiparticulate core wherein said membrane is fabricated from a microporous hydrophobic support material;
a hydrophobic liquid entrained within said membrane, said hydrophobic liquid being substantially impermeable to water and azithromycin, but being capable of changing to become substantially permeable to water and azithromycin.

47. An azithromycin-containing dosage form as defined in claim 28, comprising:
a core comprising azithromycin and at least one swelling material;
a membrane surrounding said tablet core wherein said membrane is fabricated from a microporous hydrophobic support material;
a hydrophobic liquid entrained within said membrane, said hydrophobic liquid being substantially impermeable to water and azithromycin, but being capable of changing to become substantially permeable to water and azithromycin.

48. A dosage form as defined in claim 29, comprising:
a core comprising azithromycin and at least one swelling material;
a membrane surrounding said multiparticulate core wherein said membrane is fabricated from a microporous hydrophobic support material;

a hydrophobic liquid entrained within said membrane, said hydrophobic liquid being substantially impermeable to water and azithromycin, but being capable of changing to become substantially permeable to water and azithromycin.

49. An azithromycin-containing dosage form as defined in claim 28, comprising:

a core comprising azithromycin and at least one swelling material and/or at least one osmagent;

a membrane surrounding said tablet core wherein said membrane is substantially impermeable to azithromycin and labile to enzymes produced by bacteria which inhabit the colon.

50. An azithromycin-containing dosage form as defined in claim 29, comprising:

a core comprising azithromycin and at least one swelling material and/or at least one osmagent;

a membrane surrounding said multiparticulate core wherein said membrane is substantially impermeable to azithromycin and labile to enzymes produced by bacteria which inhabit the colon.

51. An azithromycin-containing dosage form as defined in claim 49, wherein said membrane comprises a polymer comprising at least one ethylenically unsaturated monomer crosslinked by a substituted or unsubstituted divinylazobenzene.

52. An azithromycin-containing dosage form as defined in claim 50, wherein said membrane comprises a polymer comprising at least one ethylenically unsaturated monomer crosslinked by a substituted or unsubstituted divinylazobenzene.

53. An azithromycin-containing dosage form as defined in claim 49, wherein said membrane comprises at least one polysaccharide.

54. An azithromycin-containing dosage form as defined in claim 50, wherein said membrane comprises at least one polysaccharide.

55. An azithromycin-containing dosage form as defined in claim 28, in the form of a capsule comprising two interpenetrating pieces, a first male piece comprising a water-swellable material, which swells to effect disengagement of a second female piece upon administration to said mammal.

56. A method of treating a mammal with azithromycin with a reduced incidence of gastrointestinal side effects relative to a bolus oral dose, said method comprising administering to said mammal an azithromycin-containing dosage form as defined in claim 2.

57. An azithromycin-containing dosage form according to claim 1 or claim 2 comprising:

a tablet comprising azithromycin and a swelling material,

a membrane around said tablet, wherein said membrane possesses pores through which said azithromycin and swelling material may exit, or wherein said membrane contains water-soluble porosigens which leach out of said membrane in the aqueous use environment providing pores through which said azithromycin and swelling material may exit.

58. An azithromycin-containing dosage form according to claim 1 or claim 2 comprising:

core multiparticulate comprising azithromycin and a swelling material,

a membrane around each said core multiparticulate, wherein said membrane possesses pores through which said azithromycin and swelling material may exit, or wherein said membrane contains water-soluble porosigens which leach out of said membrane in the aqueous use environment providing pores through which said azithromycin and swelling material may exit.

59. A dosage form as defined in claim 2 in the form of a coated bi-layer tablet, wherein one layer of said tablet comprises a water-swellable composition and the second layer of said tablet comprises a dispensible azithromycin composition, said tablet being coated with a water-permeable membrane which is substantially impermeable to azithromycin, and which contains one or more perforations or passageways for exposing the azithromycin-containing composition to the use environment.

60. A dosage form as defined in claim 2 in the form of a coated tablet comprising a water-soluble salt of azithromycin, said tablet having a water-permeable coating which is substantially impermeable to azithromycin and substantially non-porous, said coating containing one or more perforations or passageways, for exposing the interior of the tablet to a use environment.

61. A dosage form as defined in claim 2 in the form of a coated tablet comprising azithromycin, said tablet having a porous coating which permits transport of both water and azithromycin through said porous coating.

62. A dosage form as defined in claim 2 in the form of a coated multiparticulate formulation wherein each particle comprises azithromycin and has a porous coating which permits transport of both water and azithromycin through said porous coating.

63. A dosage form as defined in claim 1, wherein said azithromycin is embedded in a matrix, which releases said azithromycin by diffusion.

64. A dosage form as defined in claim 1, comprising a reservoir of azithromycin encased in a membrane which limits the release rate of azithromycin to said GI tract by diffusion.

65. A dosage form as defined in claim 1, in the form of a multiparticulate comprising particles each of which is coated with a membrane which limits the release rate of said azithromycin by diffusion.

66. A method of treating a mammal with azithromycin with a reduced incidence of gastrointestinal side effects relative to a bolus oral dose, said method comprising dosing an azithromycin-containing dosage form as defined in claim 1.

67. A method of treating a mammal with azithromycin with a reduced incidence of gastrointestinal side effects relative to a bolus oral dose, said method comprising dosing an azithromycin-containing dosage form as defined in claim 26.

68. A dosage form as defined in claim 1 in the form of a coated bi-layer tablet, wherein one layer of said tablet comprises a water-swellable composition and the second layer of said tablet comprises a dispensible azithromycin composition, said tablet being coated with a water-permeable membrane which is substantially impermeable to azithromycin, and which contains one or more perforations for exposing the azithromycin-containing composition to the use environment.

69. A dosage form as defined in claim 1 in the form of a coated tablet comprising a water-soluble salt of azithromycin, said tablet having a water-permeable coating which is substantially impermeable to azithromycin and substantially non-porous, said coating containing one or more perforations or passageways, for exposing the interior of the tablet to a use environment.

70. A dosage form as defined in claim 1 in the form of a coated tablet comprising azithromycin, said tablet having a porous coating which permits transport of both water and azithromycin through said porous coating.

71. A dosage form as defined in claim 1 in the form of a coated multiparticulate formulation wherein each particle comprises azithromycin and has a porous coating which permits transport of both water and azithromycin through said porous coating.